

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **May 24, 2022**

**Avenue Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38114**  
(Commission File Number)

**47-4113275**  
(IRS Employer Identification No.)

**1140 Avenue of the Americas, Floor 9  
New York, New York 10036**  
(Address of Principal Executive Offices)

**(781) 652-4500**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act.  
 Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

On May 24, 2022, Avenue Therapeutics, Inc. (the "Company") received a deficiency letter (the "Nasdaq Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq"), notifying the Company that it is not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires the Company to maintain a minimum of \$2,500,000 in stockholders' equity for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement"), nor is it in compliance with either of the alternative listing standards, market value of listed securities of at least \$35 million or net income of \$500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. The Company's failure to comply with the Stockholders' Equity Requirement was based on the Company's filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, reporting the stockholders' equity of \$1,159,000.

Pursuant to the Nasdaq Letter, the Company has 45 calendar days from the date of the Nasdaq Letter to submit a plan to regain compliance and the Company intends to submit such a plan during this period. If it accepts the plan, Nasdaq can grant an extension of up to 180 calendar days from the date of the Nasdaq Letter to evidence compliance. In the event the plan is not accepted by the Nasdaq staff, or in the event the plan is accepted and the 180-day extension period granted but the Company fails to regain compliance within such plan period, the Company would have the right to a hearing before an independent panel. The hearing request would stay any suspension or delisting action pending the conclusion of the hearing process and the expiration of any additional extension period granted by the panel following the hearing.

The Company intends to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq. However, there can be no assurance that Nasdaq will grant the Company's request for an extension or that the Company will ultimately regain compliance with all applicable requirements for continued listing.

Neither the Nasdaq Letter nor the Company's noncompliance have an immediate effect on the listing or trading of the Company's common stock, which will continue to trade on The Nasdaq Capital Market under the symbol "ATXI."

**Forward-Looking Statements**

Certain matters discussed in this report may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended and the Securities Exchange Act of 1934, as amended, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words “anticipate,” “believe,” “estimate,” “may,” “expect” and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and in other reports we file with the SEC. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our: expectations for increases or decreases in expenses; expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license; our use of clinical research centers and other contractors; expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities; expectations for generating revenue or becoming profitable on a sustained basis; expectations or ability to enter into marketing and other partnership agreements; expectations or ability to enter into product acquisition and in-licensing transactions; expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidate; acceptance of our products by doctors, patients or payors; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our products; estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments; the volatility of our stock price; expected losses; and expectations for future capital requirements. The forward-looking statements contained in this report reflect our views and assumptions as of the effective date of this report. Except as required by law, we assume no responsibility for updating any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

---

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**AVENUE THERAPEUTICS, INC.**  
(Registrant)

Date: May 25, 2022

By: /s/ David Jin  
Name: David Jin  
Title: Interim Chief Executive Officer

---